

Ex. 7

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
LLOYD R. SABERSKI, M.D. on 01/12/2017

DEPOSITION OF

1 IN THE UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 IN RE NEW ENGLAND COMPOUNDING | MDL NO. 02419

5 PHARMACY, INC. PRODUCTS LIABILITY | DOCKET NO.

6 LITIGATION | 1:13-MD-2419-RWZ

7 THIS DOCUMENT RELATES TO:

8 All Actions

9
10 Deposition of LLOYD R. SABERSKI, M.D.

11 Baltimore, Maryland

12 Thursday, January 12, 2017

13 10:00 a.m.

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20 Reported by: Angela McKinney, Court Reporter



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<p style="text-align: right;">Page 102</p> <p>1 use, you consider the risk to the patient and I guess</p> <p>2 the percentage risk. But when you are considering the</p> <p>3 risk -- hold on. Let me finish. If it's a difference</p> <p>4 of .02 percent risk versus .3 percent risk or</p> <p>5 something, it's an increased -- it might be an</p> <p>6 increased risk, but it's insignificant, isn't it?</p> <p>7 Don't you have to consider that?</p> <p>8 A No. You are making a mistake here. Before</p> <p>9 you consider the risk benefit profile or the risk</p> <p>10 profile, you have to see is there benefit.</p> <p>11 Q So you have to know the numbers, don't you?</p> <p>12 A Before you get there, you have to decide if</p> <p>13 I'm going to use this product, is there a benefit.</p> <p>14 Once you have established that there is a benefit, then</p> <p>15 you can start conjugating on the numbers. But here in</p> <p>16 this case, there is no benefit. There has never been a</p> <p>17 benefit. There is no reason to use this product. So</p> <p>18 nobody who is rationally thinking of this can find an</p> <p>19 arguable reason to offer the product.</p> <p>20 Now, if there is a reason for doing it,</p> <p>21 let's say the patient has some weird allergy or some</p> <p>22 weird intolerance or something weird and they go to the</p>	<p style="text-align: right;">Page 104</p> <p>1 because the problem she associated with triamcinolone</p> <p>2 and betamethasone have nothing to do with</p> <p>3 preservatives; had everything to do with the</p> <p>4 mineralocorticoid and glucocorticoid activities of the</p> <p>5 drugs they inject. It had nothing to do with</p> <p>6 preservatives, so her argument made no sense</p> <p>7 scientifically.</p> <p>8 Yes, she had a concern. She had some</p> <p>9 problems with betamethasone and triamcinolone. She was</p> <p>10 open to using a different product. It was mentioned to</p> <p>11 her by one of her colleagues. She went ahead and</p> <p>12 ordered it. No due diligence.</p> <p>13 Q And in her mind, there was a benefit and a</p> <p>14 different therapeutic effect by using NECC's drugs</p> <p>15 compared to betamethasone and triamcinolone, right?</p> <p>16 A Well, I don't recall that. But even if</p> <p>17 there was, it's not substantiated in the literature.</p> <p>18 All three products, Depo-Medrol, triamcinolone and</p> <p>19 betamethasone, the outcomes are thought to be</p> <p>20 clinically the same.</p> <p>21 Q Would you agree that there was some</p> <p>22 contingent of respected pain physicians who believed</p>
<p style="text-align: right;">Page 103</p> <p>1 compounding pharmacist, they can make something up</p> <p>2 that's appropriate for that patient. At that point, we</p> <p>3 can talk about the appropriateness of the risk. But</p> <p>4 you can never manufacture products at a compounding</p> <p>5 pharmacy. If you start manufacturing it -- first of</p> <p>6 all, it's against the law. They can't do that.</p> <p>7 Q So you are saying that there is absolutely</p> <p>8 no benefit to compounding pharmacies; it's just an</p> <p>9 increased risk?</p> <p>10 A For injectable deposit steroids, yes.</p> <p>11 Q And you read Dr. Bhambhani's deposition,</p> <p>12 right?</p> <p>13 A I have.</p> <p>14 Q Okay. And you read that she believed there</p> <p>15 was a benefit in this case to using the drugs from</p> <p>16 NECC, right?</p> <p>17 A Not only was she wrong, she was wrong by</p> <p>18 more than a decade.</p> <p>19 Q Well, let me step back. You saw her</p> <p>20 discussion, I hope, about using her experience using</p> <p>21 triamcinolone and betamethasone. Do you recall that?</p> <p>22 A Oh, I do, very much so. She is confused</p>	<p style="text-align: right;">Page 105</p> <p>1 that there was a risk associated with injecting</p> <p>2 steroids with preservative into the spine?</p> <p>3 A Well, certainly that began with the sounding</p> <p>4 of Dewey Nelson back in the '70s, but that issue was</p> <p>5 completely arrested certainly by late 19 -- certainly</p> <p>6 by the mid '90s. So that issue was a non-issue in the</p> <p>7 '90s. Plenty of articles have shown that. And we're</p> <p>8 talking about epidural injection. There is certainly</p> <p>9 some concern about intrathecal injection, but not</p> <p>10 epidural injection. So there is no risk to patients</p> <p>11 with epidural injections and there is not a single</p> <p>12 society, there is not a single article that has been</p> <p>13 published that says that epidural injections with</p> <p>14 manufactured steroids causes arachnoiditis.</p> <p>15 Q So it used to be of concern, and you say the</p> <p>16 guy who brought it up, Dewey, that he was discredited</p> <p>17 or something?</p> <p>18 A No, he wasn't discredited. His concerns</p> <p>19 were -- this gets really interesting. His concern was</p> <p>20 about polyethylene glycol. That was the product he was</p> <p>21 concerned about and he was concerned about intrathecal</p> <p>22 injections. Then when they started doing epidural</p>

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Pages 146..149

<p style="text-align: right;">Page 146</p> <p>1 A Yes.</p> <p>2 Q You are aware of that?</p> <p>3 A Yes.</p> <p>4 Q Have you seen the audit report?</p> <p>5 A I have at one time. I've not looked at that</p> <p>6 recently.</p> <p>7 Q Would you agree at least that Brigham and</p> <p>8 Women's found NECC to be a safe supplier of drugs and</p> <p>9 they were then allowed to continue ordering drugs from</p> <p>10 NECC?</p> <p>11 MR. COREN: Objection as to form.</p> <p>12 You can answer.</p> <p>13 A That was the conclusion of the report, but</p> <p>14 my recollection is that they never actually went in to</p> <p>15 look at the clean room.</p> <p>16 BY MR. KIRBY:</p> <p>17 Q You are not a microbiologist, are you?</p> <p>18 A I am not.</p> <p>19 Q Do you typically inspect clean rooms?</p> <p>20 A Typically, no. Have I done it? Yes.</p> <p>21 Q Do you typically do inspections and things</p> <p>22 like that?</p>	<p style="text-align: right;">Page 148</p> <p>1 amount of due diligence that Dr. Bhambhani or other</p> <p>2 health care providers could have done in your mind to</p> <p>3 make NECC a supplier of preservative-free MPA?</p> <p>4 MR. COREN: Objection to form.</p> <p>5 A Yes. The first order of business is they</p> <p>6 have to establish whether there is a need for having</p> <p>7 it. So if she would have done due diligence, she would</p> <p>8 have found there was no need and therefore would have</p> <p>9 quickly saved her patients' complications by never</p> <p>10 using NECC. So that's -- and we know she did no due</p> <p>11 diligence because she admitted it in her deposition.</p> <p>12 BY MR. KIRBY:</p> <p>13 Q But you can't say if she had done due</p> <p>14 diligence whether she would have found there was a drug</p> <p>15 shortage or not?</p> <p>16 MR. COREN: Objection to the form.</p> <p>17 A She would have found that to need a</p> <p>18 compounding pharmacy, you have to have a special need</p> <p>19 that's specific enough to write a prescription</p> <p>20 specific.</p> <p>21 BY MR. KIRBY:</p> <p>22 Q You said I think before that if there was a</p>
<p style="text-align: right;">Page 147</p> <p>1 A No.</p> <p>2 Q But you would agree that the conclusion</p> <p>3 drawn was that Brigham and Women's was -- hold on. Let</p> <p>4 me find it. That they were approved for sterile</p> <p>5 compounding preparations for Brigham and Women's</p> <p>6 Hospital?</p> <p>7 MR. COREN: Objection to form.</p> <p>8 A I would have to look at the actual sentence,</p> <p>9 but I do know that Brigham and Women's did continue to</p> <p>10 do business with NECC.</p> <p>11 BY MR. KIRBY:</p> <p>12 Q So you are kind of drawing the conclusion?</p> <p>13 A Yes.</p> <p>14 Q For the record, that's Exhibit 302.</p> <p>15 When we talked earlier, you don't think that</p> <p>16 Dr. Bhambhani needed -- or anybody for that matter had</p> <p>17 to go and inspect NECC themselves, right?</p> <p>18 MR. COREN: Objection as to form.</p> <p>19 BY MR. KIRBY:</p> <p>20 Q Before using them?</p> <p>21 A No.</p> <p>22 Q Let me cut to the chase. Is there any</p>	<p style="text-align: right;">Page 149</p> <p>1 need, meaning there wasn't a commercially -- well, two</p> <p>2 things: That if there wasn't a commercially available</p> <p>3 product of methylprednisolone acetate</p> <p>4 preservative-free, then she could get it from a</p> <p>5 compounding pharmacy, right?</p> <p>6 A No. There were other products that were</p> <p>7 equally as good that would substitute. Nobody has ever</p> <p>8 demonstrated any improvement of Depo-Medrol or</p> <p>9 methylprednisolone over the triamcinolone and</p> <p>10 betamethasone. And as I mentioned earlier, there is</p> <p>11 data accruing now that Depo-Medrol may have more of a</p> <p>12 hazard in terms of a gluten issue and emboli.</p> <p>13 Q And that's your opinion?</p> <p>14 A No. That's been published.</p> <p>15 Q But you are not foreclosing that other</p> <p>16 reasonably prudent and trained physicians might have a</p> <p>17 different opinion?</p> <p>18 A About what?</p> <p>19 Q That methylprednisolone acetate is better or</p> <p>20 that there is a reason not to use triamcinolone or</p> <p>21 betamethasone.</p> <p>22 A Nobody has that opinion -- well, I don't</p>



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